AMENDMENTS TO THE CLAIMS

1. (Currently Amended) A solid ~~dispersion~~ pharmaceutical composition comprising an active ingredient selected among tacrolimus and analogues thereof dispersed or dissolved in polyethylene glycol having an average molecular weight of at least 1500 and a poloxamer, wherein ~~a hydrophilic or water miscible vehicle, wherein the melting point of the vehicle is at least 20° C~~ and the active ingredient is present therein in a concentration of between about 0.01 w/w% and about 15 w/w% ~~to form a solid dispersion or solid solution at ambient temperature~~ and the pharmaceutical composition is free of organic solvent.

2. (Withdrawn – Currently Amended) The solid ~~dispersion~~ pharmaceutical composition according to claim 1, wherein the analogue exhibits pharmacological and/or therapeutic~~al~~ activity at least equivalent to that of tacrolimus.

3. (Currently Amended) The solid ~~dispersion~~ pharmaceutical composition according to claim 1, wherein the active ingredient is partly dissolved in the vehicle to form a mixture of solid dispersion and solid solution at ambient temperature.

4. (Currently Amended) The solid ~~dispersion~~ pharmaceutical composition according to claim 1, wherein the active ingredient is fully dissolved in the vehicle to form a solid solution at ambient temperature.

5. (Currently Amended) The solid ~~dispersion~~ pharmaceutical composition according to claim 1, wherein the hydrophilic or water-miscible vehicle has a melting point of at least 30°C.

6. (Currently Amended) The solid ~~dispersion~~ pharmaceutical composition according to claim 1, wherein the concentration of the active ingredient in the hydrophilic or water-miscible vehicle is at the most 10w/w%.

7. (Currently Amended) The solid ~~dispersion~~ pharmaceutical composition according to claim 1, wherein the concentration of the active ingredient in the hydrophilic or water-miscible vehicle is at least about 0.05w/w%.

8. (Currently Amended) The solid ~~dispersion~~ pharmaceutical composition according to claim 1, wherein at least 50 w/w% of the active pharmaceutical ingredient is released within about 30 minutes, when tested in any dissolution test according to USP using an aqueous dissolution medium.

9. (Currently Amended) The solid ~~dispersion~~ pharmaceutical composition according to claim 1, wherein at least 75 w/w% of the active pharmaceutical ingredient is released within about 40 minutes, when tested in any dissolution test according to USP using an aqueous dissolution medium.

10. (Currently Amended) The solid ~~dispersion~~ pharmaceutical composition according to claim 1, wherein at least 90 w/w% of the active pharmaceutical ingredient is released within about 60 minutes, when tested in any dissolution test according to USP using an aqueous dissolution medium.

11. (Currently Amended) The solid ~~dispersion~~ pharmaceutical composition according to claim 1, wherein the hydrophilic or water-miscible vehicle is selected from the group consisting of polyethylene glycols, polyoxyethylene oxides, poloxamers, polyoxyethylene stearates, poly-epsilon caprolactone, polyglycolized glycerides ~~such as Gelucire®~~, and mixtures thereof.

12. (Withdrawn - Currently Amended) The solid ~~dispersion~~ pharmaceutical composition according to claim 1, wherein the hydrophilic or water-miscible vehicle is selected from the group consisting of polyvinylpyrrolidones, polyvinyl- polyvinylacetate copolymers (PVP-PVA), polyvinyl alcohol (PVA), polymethacrylic polymers ~~(Eudragit RS; Eudragit RL, Eudragit NE, Eudragit E)~~, cellulose derivatives ~~including hydroxypropyl methylcellulose (HPMC), hydroxypropyl cellulose~~

~~(HPC), methylcellulose, sodium carboxymethylcellulose, hydroxyethyl cellulose, pectins, cyclodextrins, galactomannans, alginates, carragenates, xanthan gums~~ and mixtures thereof.

13. (Currently Amended) The solid ~~dispersion~~ pharmaceutical composition according to claim 1, wherein the vehicle is a polyethylene glycol (PEG).

14. (Currently Amended) The solid ~~dispersion~~ pharmaceutical composition according to claim 13, wherein the polyethylene glycol has an average molecular weight of at least 1500.

15. (Currently Amended) The solid ~~dispersion~~ pharmaceutical composition according to claim 1 comprising a mixture of two or more hydrophilic or water-miscible vehicles.

16. (Currently Amended) The solid ~~dispersion~~ pharmaceutical composition according to claim 15, wherein the mixture comprises a polyethylene glycol and a poloxamer in a proportion of between 1: 3 and 10: 1~~, preferably between 1: 1 and 5: 1, more preferably between and 3:2 4:1, especially between 2:1 and 3:1, in particular about 7:3~~.

17. (Currently Amended) The solid ~~dispersion~~ pharmaceutical composition according to claim 16, wherein the poloxamer is poloxamer 188.

18. (Currently Amended) The solid ~~dispersion~~ pharmaceutical composition according to claim 16, wherein the polyethylene glycol has an average molecular weight of about 6000 (PEG6000).

19. (Currently Amended) The solid pharmaceutical composition according to claim 1, comprising ~~A composition comprising the solid dispersion according to claim 1 and~~ one or more pharmaceutically acceptable excipients.

20. (Currently Amended) The solid pharmaceutical composition according to claim 19, wherein the pharmaceutically acceptable excipients are selected from the group consisting of fillers, disintegrants, binders and lubricants.

21. (Currently Amended) The solid pharmaceutical composition according to claim 19 in particulate form~~, for example in powder form~~.

22. (Currently Amended) The solid pharmaceutical composition according to claim 21, wherein the particles have a geometric weight mean diameter d_{gw} from about 10 um to about 2000 um~~, preferably from about 20 um to about 2000 um, especially from about 50 um to about 300 um~~.

23. (Currently Amended) The solid pharmaceutical composition according to claim 21, wherein the particles have a geometric weight mean diameter d_{gw} from about 50 um to about 300 um.

24. (Currently Amended) A solid dosage form comprising the solid pharmaceutical composition according to claim 19, which is a solid oral dosage form.

25. (Currently Amended) The solid dosage form according to claim 24, which is a unit dosage form.

26. (Currently Amended) The solid dosage form according to claim 24, which further comprises a pharmaceutically acceptable additive selected from the group consisting of flavoring agents, coloring agents, taste-masking agents, pH-adjusting agents, buffering agents, preservatives, stabilizing agents, anti-oxidants, wetting agents, humidity-adjusting agents, surface-active agents, suspending agents, absorption enhancing agents and release modifying agents.

27. (Currently Amended) The solid dosage form according to claim 24, wherein at least one pharmaceutical acceptable excipient is selected from the group consisting of silica acid or a derivative or salt thereof ~~including silicates, silicon dioxide and polymers thereof; magnesium aluminosilicate and/or magnesium aluminometasilicate, bentonite, kaolin, magnesium trisilicate, montmorillonite and/or saponite~~.

28. (Currently Amended) The solid dosage form according to claim 24, wherein at least one pharmaceutically acceptable excipient is a silica acid or a derivative or salt thereof.

29. (Currently Amended) The solid dosage form according to claim 24, wherein at least one pharmaceutical acceptable excipient is silicon dioxide or a polymer thereof.

30. (Canceled)

31. (Currently Amended) The solid dosage form according to claim 26 comprising one or more release modifying agents selected from the group consisting of water-miscible polymers, water-insoluble polymers, oils and oily materials.

32. (Currently Amended) The solid dosage form according to claim 31, wherein the water-insoluble polymer is selected from the group consisting of ethyl cellulose, cellulose acetate, cellulose nitrate, and mixtures thereof.

33. (Currently Amended) The solid dosage form according to claim 31, wherein the oil or oily material is selected from the group consisting of hydrophilic and hydrophobic oils or oily materials.

34. (Currently Amended) The solid dosage form according to claim 31, wherein the oil or oily material is hydrophilic and selected from the group consisting of polyether glycols ~~such as polypropylene glycols ; polyoxyethylenes; polyoxypropylenes ; poloxamers ; polyglycolized glycerides such as Gelucire®~~ and mixtures thereof.

35. (Canceled)

36. (Currently Amended) The solid dosage form according to claim 31, wherein the oil or oily material is hydrophobic and selected from the group consisting of straight chain saturated hydrocarbons, sorbitan esters, paraffins; fats and oils ~~such as cacao butter, beef tallow, lard, polyether glycol esters~~; higher fatty acid, ~~such as~~ stearic acid, myristic acid, palmitic acid, higher alcohols ~~such as cetanol, stearyl alcohol~~, low melting point waxes ~~such as glyceryl monostearate, glyceryl monooleate, hydrogenated tallow, myristyl alcohol, stearyl alcohol, substituted and/or unsubstituted monoglycerides~~, substituted and/or unsubstituted diglycerides, substituted and/or

unsubstituted triglycerides, yellow beeswax, white beeswax, carnauba wax, castor wax, japan wax, acetate monoglycerides; NVP polymers, PVP polymers, acrylic polymers, and mixtures thereof.

37. (Currently Amended) The solid dosage form according to claim 36, wherein the oil or oily hydrophobic material has a melting point of at least about 20 °C.

38. (Withdrawn - Currently Amended) The solid dosage form according to claim 31, wherein the water-miscible polymer is a cellulose derivative selected from the group consisting of hydroxypropyl methylcellulose (HPMC), hydroxypropyl cellulose (HPC), methylcellulose, sodium carboxymethylcellulose, hydroxyethyl cellulose, poloxamers, polyoxyethylene stearates, poly-s-caprolactone, polyvinylpyrrolidone (PVP), polyvinylpyrrolidone-polyvinylacetate copolymer PVP-PVA, polymethacrylic polymers and polyvinyl alcohol (PVA), poly (ethylene oxide) (PEO) and mixtures thereof.

39. (Withdrawn - Currently Amended) The solid dosage form according to claim 38, wherein the polymethacrylic polymers are selected among Eudragit® RS, Eudragit® RL, Eudragit® NE and Eudragit® E.

40. (Currently Amended) The solid dosage form according to claim 31, which is entero-coated using a water-miscible polymer having a pH-dependant solubility in water.

41. (Currently Amended) The solid dosage form according to claim 40, wherein the water-miscible polymer is selected from the group consisting of polyacrylamides; phthalate derivatives ~~such as acid phthalate of carbohydrates including amylose acetate phthalate~~, cellulose acetate phthalate, cellulose acetate terephtahalate, cellulose acetate isophthalate, other cellulose ester phthalates, cellulose ether phthalates, hydroxypropyl cellulose phthalate, hydroxypropylcellulose acetate phthalate, hydroxypropyl ethylcellulose phthalate, hydroxypropyl methylcellulose phthalate (HMPCP), methylcellulose phthalate, methyl cellulose acetate phthalate, polyvinyl acetate phthalate, polyvinyl acetate hydrogen phthalate, sodium cellulose acetate phthalate, starch acid phthalate ; phthalate of other compounds including polyvinyl acetate phthalate

(PVAP); other cellulose derivatives including hydroxypropyl methylcellulose acetate succinate (HPMCAS), carboxymethylcellulose, cellulose acetate trimellitate; alginates ; carbomers; polyacrylic acid derivatives ~~such as acrylic acid and acrylic ester copolymers~~, polymethacrylic acid and esters thereof, poly acrylic methacrylic acid copolymers, methacrylic acid copolymers ~~(for example Eudragit L and Eudragite S)~~; styrene-maleic acid dibutyl phthalate copolymer, styrene-maleic acid polyvinylacetate phthalate copolymer, styrene and maleic acid copolymers ; shellac, starch glycolat; polacrylin ; vinyl acetate and crotonic acid copolymers and mixtures thereof.

42. (Currently Amended) The solid dosage form according to claim 40, which upon oral administration to a mammal in need thereof releases at the most about 10 w/w%, preferably at the most about 7.5 w/w% ~~, more preferably at the most about 5 w/w%, especially at the most about 2 w/w% of the total amount of active ingredient within the first 3 hours, preferably within 2 hours, more preferably within 1 hours, in particular within about 30 minutes after administration~~.

43. (Currently Amended) The solid dosage form according to claim 24, wherein the solid dosage form upon oral administration to a mammal in need thereof provides an AUC or C_{max} of tacrolimus that is ~~essentially bioequivalent~~ 80%-125% of that provided by a capsule dosage form approved under U.S. Food and Drug Administration NDA No. 050708, wherein the dose of tacrolimus administered with the solid dosage form ~~or a similar commercially available tacrolimus-containing product when administered in a dose that~~ is at the most about 85% w/w of the dose of tacrolimus administered in the form of the capsule dosage form approved under NDA No. 050708 ~~or a similar commercially available tacrolimus-containing product~~.

44. (Currently Amended) The solid dosage form according to claim 24, wherein the solid dosage form upon oral administration to a mammal in need thereof releases at least about 50% w/w of the active ingredient within 24 hours ~~, preferably within about 20 hours, more preferably within about 18 hours, especially within about 15 hours, in particular within about 12 hours~~.

45-50 (Canceled)

51. (Currently Amended) A method for the preparation of the ~~solid dispersion~~ solid pharmaceutical composition according to claim 1, the method comprising the steps of (a) dispersing and/or dissolving tacrolimus or an analogue thereof in a polyethylene glycol having an average molecular weight of at least 1500 and a poloxamer to form a mixture, and (b) spraying the mixture onto a solid carrier ~~hydrophilic or water-miscible vehicle~~ to obtain the solid pharmaceutical composition ~~a solid dispersion and/or solid solution at ambient temperature~~.

52. (New) The method according to claim 51, wherein step (a) is performed in the absence of an organic solvent.

53. (New) A solid pharmaceutical composition prepared according to the method of claim 51.

54. (New) A solid pharmaceutical composition prepared according to the method of claim 52.

55. (New) The solid pharmaceutical composition according to claim 1, wherein the solid pharmaceutical composition is a tablet.

56. (New) A solid pharmaceutical composition comprising an active ingredient selected among tacrolimus and analogues thereof dispersed or dissolved, in the absence of an organic solvent, in polyethylene glycol having an average molecular weight of at least 1500 and a poloxamer, wherein the active ingredient is present therein in a concentration of between about 0.01 w/w% and about 15 w/w% and the pharmaceutical composition is free of organic solvent.